REMARKS

In view of the above amendments and the following remarks, Applicants request reconsideration and allowance of the claims.

Claims 21-23, 25-36, 38-48 and 50-57 are pending with claims 21, 36, 39, and 47 being independent. Claims 21, 36, 39, and 47 have been amended. Claim 37 has been cancelled and incorporated into claim 36. The amendments to the claims find support in the application as filed at least at page 27, line 26 through page 29. line 2, and Figures 76-79. New claims 54-57 find support in the specification at page 28, lines 19-22. No new matter has been added with these amendments to the claims.

Claims 21-23, 27-31, 33, 35, 36, 39, 45-48 and 52-53 have been rejected as being anticipated by Gittings (US 7,025,773). As amended, claim 21 is directed to a medical device for placing against a tissue surface within a mammalian to cover an outer surface of the tissue and appose opposite edges of an opening in the tissue and at least partially conform to the shape of the tissue surface to close the opening in the tissue.

The device includes at least one layer of a biocompatible material and at least one layer of a biocompatible superelastic/shape memory material. The biocompatible superelastic/shape memory material is in the form of a sheet having an upper side and a lower side having a pair of opposite edges. The sheet consists of one piece of a single material and is covered over at least a portion of the upper side and at least a portion of the lower side by the biocompatible material without the use of an adherent material. The biocompatible superelastic/shape memory material is configured to have a curved configuration in an unconstrained shape if the biocompatible superelastic/shape memory material is configured to have a superelastic property or to have a curved configuration in a heated, transformed shape if the biocompatible superelastic/shape memory material is configured to have a shape memory property. The opposite edges of the lower side of the layer of the biocompatible superelastic/shape memory material moves in the direction of one another when caused to be in the unconstrained shape or the heated, transformed shape from the constrained or unheated/untransformed shape, respectively, such that the opposite edges of the lower side of the superelastic/shape memory material cause an apposition of the

opposite edges of the opening in the tissue with at least a portion of the lower side covering the opening in the tissue.

Gittings is directed to conduits that may be placed in a blood vessel to provide a source of blood flow. As illustrated in Figs. 5a-5d of Gittings, the conduit may be in the form of a mesh stent 26 that is lined with a second material, such as a PTFE liner. See Gittings, col. 7, lines 1-31. The figures illustrate the stent placed within an opening in the vessel and expanded to fill the opening and permit the stent to pass from the lumen of the blood vessel through an opening of the vessel to outside of the vessel. Gittings, however, fails to describe or suggest a medical device for placing against a tissue surface within a mammalian to cover an outer surface of the tissue and appose opposite edges of an opening in the tissue and at least partially conform to the shape of the tissue surface to close the opening in the tissue. In contrast, Gittings neither apposes opposite edges of an opening in the tissue nor partially conforms to the shape of the tissue surface to close the opening in the tissue.

First, Gittings does not appose opposite edges of an opening in the tissue. Instead, Gittings is configured to ensure that the opening into the vessel remains open. In particular, Figs. 5a-5d and 6 illustrate the stent 26 being deployed within the opening in the vessel and the opening being maintained open by the expanded stent.

Second, Gittings does not partially conform to the shape of the tissue surface to close the opening in the tissue. Instead, Gittings is expanded to have a shape that changes the shape of the tissue surface, not to at least partially conform to the shape of the tissue surface. Moreover, in so doing, Gittings does not close the opening in the tissue but insures that it remains open and provides a conduit for blood to flow through the conduit through the opening. Again, Figs. 5a and 5b illustrate the stent being opened into the vessel and changing the shape of the vessel opening to conform to the shape of the stent and keep the vessel opening from closing.

As such independent claim 21 and dependent claims 22-23 and 25-35 are allowable over Gittings.

Independent claim 36 is directed to a medical device for placing against a tissue surface of a mammalian to resist remodeling of the heart caused by congestive heart failure while being

configured to assist the heart during systole. The device includes multiple arms and a base configured to form a concave shape, the arms extending outwardly from the base, the arms and base being configured from at least one layer of a biocompatible material; and at least one layer of a biocompatible superelastic/shape memory material.

The biocompatible superelastic/shape memory material is in the form of a sheet having an upper side and a lower side, the sheet consisting of one piece of a single material and being covered over at least a portion of the upper side and at least a portion of the lower side by the biocompatible material without the use of an adherent material, and the biocompatible superelastic/shape memory material being configured to have a curved configuration in an unconstrained shape if the biocompatible superelastic/shape memory material is configured to have a superelastic property or to have a curved configuration in a heated, transformed shape if the biocompatible superelastic/shape memory material is configured to have a shape memory property. The arms move in the direction of one another when caused to be in the unconstrained shape or the heated, transformed shape from the constrained or unheated/untransformed shape, respectively.

As noted above, Gittings is directed to stents placed within an opening in a blood vessel. As such, Gittings fails to describe or suggest a medical device for placing against a tissue surface of a mammalian to resist remodeling of the heart caused by congestive heart failure while being configured to assist the heart during systole. Gittings also fails to describe or suggest a device that includes multiple arms and a base configured to form a concave shape, the arms extending outwardly from the base, the arms and base being configured from at least one layer of a biocompatible material and at least one layer of a biocompatible superelastic/shape memory material.

At most, Gittings describes a stent formed from a flat sheet that is unrolled to an expanded orientation. See Gittings, col. 7, lines 1-7. Although Gittings describes how a PTFE liner may be attached to a wire mesh stent, Gittings does not discloses how such a liner would be attached to a flat sheet stent. As noted above, Gittings discloses his stent as being inserted into an opening in a blood vessel. This cannot be characterized as being the same as or similar to

being placed against a tissue surface to resist remodeling of the heart caused by congestive heart failure.

Further, Gittings does not disclose a medical device in which the arms move in the direction of one another when caused to be in the unconstrained shape or the heated, transformed shape from the constrained or unheated/untransformed shape, respectively. Gittings does not disclose an equivalent device with a base and arms extending away from the base. Thus, Gittings does not disclose arms that move in the direction of one another. For at least these reasons, claim 36 and dependent claim 38 are allowable over Gittings.

Independent claim 39 is directed to a method of applying a medical device to a tissue surface within a mammalian body to cover an outer surface of the tissue surface and appose opposite edges of an opening in the tissue and at least partially conform to the shape of the tissue surface to partially or completely close the opening. Like independent claim 21, claim 39 recites a medical device for placing against a tissue surface within a mammalian to cover an outer surface of the tissue and appose opposite edges of an opening in the tissue and at least partially conform to the shape of the tissue surface to close the opening in the tissue. As such, for the reasons that claim 21 is allowable over Gittings, claim 39 and dependent claims 40-46 are allowable over Gittings.

Independent claim 47 is directed to a method of treating a condition in a mammalian body that is treatable by placing a medical device against an outer tissue surface to compress the outer tissue surface. The method includes advancing a medical device to an outer tissue surface; pressing the medical device against the outer tissue surface; releasing the medical device from expansion such that it compresses against the outer tissue surface; and leaving the medical device compressed against the tissue surface to compress the tissue. The medical device includes at least one layer of a biocompatible material and at least one layer of a biocompatible superelastic/shape memory material, the biocompatible superelastic/shape memory material being in the form of a sheet having an upper side and a lower side. The sheet consists of one piece of a single material and is covered over at least a portion of the upper side and at least a portion of the lower side by the biocompatible material without the use of an adherent material, and the biocompatible superelastic/shape memory material is configured to have a curved

configuration in an unconstrained shape if the biocompatible superelastic/shape memory material is configured to have a superelastic property or to have a curved configuration in a heated, transformed shape if the biocompatible superelastic/shape memory material is configured to have a shape memory property.

Gittings does not describe or suggest to a method of treating a condition in a mammalian body that is treatable by placing a medical device against an outer tissue surface to compress the outer tissue surface. Instead, Gittings discloses placing a stent within an opening of a blood vessel to provide a conduit for blood flow through the conduit. The Gittings stent does not compress an outer tissue surface but instead maintains an opening in a vessel. As such, claim 47 and dependent claims 48 and 50-53 are allowable over Gittings.

Dependent claims 25 and 38 are rejected as being obvious over the combination of Gittings in view of McNamara (US 6,004,347). McNamara discloses prongs with barbs that attach to the vessel wall. McNamara, however, fails to cure the deficiency of Gittings to describe or suggest a medical device for placing against a tissue surface within a mammalian to cover an outer surface of the tissue and appose opposite edges of an opening in the tissue and at least partially conform to the shape of the tissue surface to close the opening in the tissue, as recited in claim 21. As such, claim 25 is allowable over the combination of Gittings and McNamara.

Similarly, like Gittings, McNamara fails to describe or suggest a medical device for placing against a tissue surface of a mammalian to resist remodeling of the heart caused by congestive heart failure while being configured to assist the heart during systole, as recited in claim 36, from which claim 38 depends. Like Gittings, McNamara also fails to describe or suggest a device that includes multiple arms and a base configured to form a concave shape, the arms extending outwardly from the base, the arms and base being configured from at least one layer of a biocompatible material; and at least one layer of a biocompatible superelastic/shape memory material, as recited in claim 36. As such, claim 38 is allowable over the combination of Gittings and McNamara.

Claim 26 is rejected as being obvious over Gittings in view of McNamara and Forber (US 5,733,294). Forber discloses cardiovascular occlusion devices formed from wires and bands. Forber fails to cure the deficiency of Gittings and McNamara to describe or suggest a medical device for placing against a tissue surface within a mammalian to cover an outer surface of the tissue and appose opposite edges of an opening in the tissue and at least partially conform to the shape of the tissue surface to close the opening in the tissue, as recited in claim 21. As such, claim 25 is allowable over the combination of Gittings, McNamara, and Forber.

Claims 32 and 43 are rejected as being obvious over Gittings in view of Plaia (US 6,090,135). Plaia discloses liners that can be placed within a blood vessel to address an atheroma and restenosis. Plaia fails to cure the deficiency of Gittings to describe or suggest a medical device for placing against a tissue surface within a mammalian to cover an outer surface of the tissue and appose opposite edges of an opening in the tissue and at least partially conform to the shape of the tissue surface to close the opening in the tissue, as recited in independent claims 21 and 39. As such, dependent claims 32 and 43 are allowable over the combination of Gittings and Plaia.

Claim 34 is rejected as being obvious over Gittings in view of Narciso (US 5,419,760). Narciso discloses a stent that provides photosensitive delivery of a treatment to prevent restenosis of the vessel. Narciso fails to cure the deficiency of Gittings to describe or suggest a medical device for placing against a tissue surface within a mammalian to cover an outer surface of the tissue and appose opposite edges of an opening in the tissue and at least partially conform to the shape of the tissue surface to close the opening in the tissue, as recited in independent claims 21. As such, dependent claim 34 is allowable over the combination of Gittings and Narciso.

Claim 40 is rejected as being obvious over Gittings in view of Sigwart (US 5,443,500). Sigwart discloses a wire mesh stent that is in the form of a rolled up rectangular sheet. Sigwart fails to cure the deficiency of Gittings to describe or suggest a medical device for placing against a tissue surface within a mammalian to cover an outer surface of the tissue and appose opposite edges of an opening in the tissue and at least partially conform to the shape of the tissue surface

to close the opening in the tissue, as recited in independent claim 39. As such, dependent claim 43 is allowable over the combination of Gittings and Sigwart.

Claims 41 and 42 are rejected as being obvious over Gittings in view of Monroe (US 6,113,608). Monroe discloses a stent delivery device. Monroe fails to cure the deficiency of Gittings to describe or suggest a medical device for placing against a tissue surface within a mammalian to cover an outer surface of the tissue and appose opposite edges of an opening in the tissue and at least partially conform to the shape of the tissue surface to close the opening in the tissue, as recited in independent claim 39. As such, dependent claims 41 and 42 are allowable over the combination of Gittings and Monroe.

Claim 44 is rejected as being obvious over Gittings in view of McNamara. McNamara fails to cure the deficiency of Gittings to describe or suggest a medical device for placing against a tissue surface within a mammalian to cover an outer surface of the tissue and appose opposite edges of an opening in the tissue and at least partially conform to the shape of the tissue surface to close the opening in the tissue, as recited in independent claim 39. As such, dependent claim 44 is allowable over the combination of Gittings and McNamara.

Claim 45 is rejected as being obvious over Gittings in view of Narciso. Narciso fails to cure the deficiency of Gittings to describe or suggest a medical device for placing against a tissue surface within a mammalian to cover an outer surface of the tissue and appose opposite edges of an opening in the tissue and at least partially conform to the shape of the tissue surface to close the opening in the tissue, as recited in independent claim 39. As such, dependent claim 45 is allowable over the combination of Gittings and Narciso.

Claim 50 is rejected as being obvious over Gittings in view of McNamara. McNamara fails to cure the deficiency of Gittings to describe or suggest a method of treating a condition in a mammalian body that is treatable by placing a medical device against an outer tissue surface to compress the outer tissue surface, as recited in claim 47. Instead, McNamara discloses placing the device within a blood vessel. As such, dependent claim 50 is allowable over the combination of Gittings and McNamara.

Claim 51 is rejected as being obvious over Gittings in view of Yang (US 6,517,575). Yang is directed to a multilayer device that includes one layer of a material capable of absorbing a liquid and a second layer that is not as capable of absorbing fluid to thereby cause deformation of the device upon liquid absorption. The device is inserted into a blood vessel as a stent. Yang fails to cure the deficiency of Gittings to describe or suggest a method of treating a condition in a mammalian body that is treatable by placing a medical device against an outer tissue surface to compress the outer tissue surface, as recited in claim 47. Instead, Yang discloses placing the device within a blood vessel. As such, dependent claim 51 is allowable over the combination of Gittings and Yang.

Dependent claims 54-57 depend from independent claims 21, 36, 39 and 47, respectively, and are allowable over the art of record for at least the same reasons that claims 21, 36, 39 and 47 are allowable.

In conclusion, Applicants believe all claims are allowable and request a notice of allowance. The Examiner is urged to contact the undersigned should she have any questions. Applicants claim a small entity status. Applicants have added four new claims and cancelled a total of three claims. As such, Applicants are separately paying by credit card the fees due for an additional claim as a small entity.

Respectfully submitted,

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